REMARKS

Claims 12-14, as amended, and new claims 18-27 appear in this application for the Examiner's review and consideration.

Applicants now only present claims to the process of manufacture of a delivery system. Thus, claims 1-11 have been cancelled. Claim 12 has been amended to avoid dependency on claim 1 and to recite a preferred feature where the material is extruded using a twin screw extruder. Support for this change appears in the specification on paragraph [0056], page 5 of the published specification. New claims 18-27 have been added. Support for these claims appears in original claims 2-11, so that there is no issue of new matter. The amended and new claims should be entered to reduce the issues for appeal, in particular, by placing the entire application in condition for allowance.

The cancellation of claims 1-11 and 15-17 thus renders moot all rejections of those claims. Thus, the only remaining rejection is of claims 12-14 under 35 U.S.C. § 103(a) as being unpatentable over Sair *et al.* (U.S. Patent No. 4,232,047).

As previously explained, Sair discloses a food supplement concentrate of an ingestible agent encapsulated as a dispersed microphase within a matrix of encapsulating medium such as starch, protein, flour, modified starch, gum and mixtures thereof. Sair is completely silent on the use of agar agar, let alone the specific quantities of agar agar to be used or the manner of its employment. Further, agar agar as used in the present invention is different from each of the encapsulating medium mentioned in Sair, namely, starch, flour, gum, cereal, and protein. A soluble carbohydrate isolated from algae, agar agar cannot be equated with a typical gum isolated from plants. That the prehydrated form of agar agar, and not any gum, is used in the present invention further emphasizes the differences between the encapsulating materials used in the present invention and Sair.

The new process claims differ in two essential and non-obvious ways from the cited art. First of all, the inventors wish to re-emphasize the importance of the use of pre-hydrated agar agar, a material that is not disclosed in any prior art document, and which is even more relevant in screw extrusion processes. In such processes, the water content of the melt to be extruded is generally lower than with extrusion under pressure into a cold solvent as disclosed, e.g., by Barnes.

In order to mix with the remaining matrix of polymeric carriers, agar agar has to be mixed with water first (= pre-hydrated, see para [0047] and [0049]). In para [0049] the

present description instructs the skilled person as follows: Separately, the agar agar is mixed with approximately 11 times its weight in water and allowed to rehydrate. The agar agar suspension is then added to the carbohydrate solution which is then heated to remove sufficient water to form a viscous melt containing from 3 to 12% of water.

The reason for this lies in the fact that high amounts of water are necessary to plasticize agar agar. Therefore, inventors note that without prior pre-hydration, no gel formation occurs and agar agar could not be mixed with the polymeric carriers. The advantages of the present invention as disclosed on para [0025] (stability of the delivery system in water) would not become apparent without the use of pre-hydrated agar agar, which has been mentioned for the first time in the present invention.

Barnes, which in the inventors' opinion represents the closest prior art, does not disclose screw extrusion, but relies on extruding into cold solvent such as isopropyl alcohol (page 10, lines 3-23). In these kinds of processes, some type of gas pressure is used to force the melt in a vertical direction through die holes into a solvent bath placed below the extruder. In these extrusion processes, the melt contains higher amounts of water and the melt is not subjected to the high shear forces, as would be the case with screw extruders.

Accordingly, para [0051], [0052] and [0055] of the application as published detail the characteristics of screw extrusion processes, namely the fact that higher pressures are needed, the fact that the melt has a higher solids content (i.e., it contains less water), and has the advantage in that the drying step may be avoided. These advantages are unexpected in view of the art and but easily achieved by simply passing the melt through a twin screw extruder, a claimed. Thus, the present claims are patentable over Sair.

Furthermore, rather than rendering the present invention obvious, Sair teaches away from the present invention by stating that: "The essence of the present invention does not lie . . . *in the selection of any specific encapsulating material* as a protective matrix" (col. 6, lines 22-26) (emphasis added). By de-emphasizing the role of the encapsulating material and teaching that the choice of the material should not affect encapsulation, Sair leads one skilled in the art away from looking at particular matrix components. Given the teachings from Sair, a person skilled in the art would have no motivation to modify Sair, which does not even mention agar agar, to arrive at the present invention and the resulting advantages that are unexpectedly obtained by using a specific quantity of a specific matrix material in a specific manner. Thus, the rejection based on Sair should be withdrawn.

The office action states that differences in concentration do not support patentability unless the difference is critical. This has been proven in the present invention because the use of relatively low quantities of agar agar in the delivery system of the present invention enable it to be a successful alternative to prior art capsules that consist totally of agar agar. As agar agar is an expensive raw material, its replacement by starch or starch derivatives (e.g., maltodextrin) in the polymeric matrix of the present invention is an important goal for designing an economic process. This substitution also contributes to the final properties of capsules wherein capsules having 1-7% of agar agar will be totally different from capsules consisting to 100% of agar agar. For this reason, the statement in the office action is not correct, since different concentrations generally result in different properties. As an example, the capsules of the previously cited Goto et al. reference do not show sufficient release in water, but need generally to be swallowed and exposed to the acidic acid of the stomach to result in significant release of the active agent from the capsules. Accordingly, Goto is silent on the release characteristics of their capsules when placed in water, because it is primarily about replacement of gelatin in capsules for medicaments (see page 2, lines 8-19). In addition, Goto does not mention a process that uses screw extrusion at all. Sair, on the other hand, does not mention agar agar at all, and, as a consequence, does not mention the importance of providing this ingredient in a pre-hydrated form nor of using the relatively small amounts hat are present in the presently claimed process. With this important technical teaching missing, Sair is not related to the subject matter of the present invention. Accordingly, Applicants respectfully request that all rejections under § 103 based on Sair should be withdrawn.

In view of the above, the entire application is believed to be in condition for allowance, early notification of such would be appreciated. Should the Examiner not agree, a personal or telephonic interview is respectfully requested to discuss any remaining issues in order to expedite the eventual allowance of the claims.

Respectfully submitted,

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